REMARKS

Applicants again want to thank the Examiner for the courtesy of conducting a telephone interview with their representative on April 22, 2003.

Claims 1, 2, 5, 6, 8, 9, 11, 12, 14, 15, 17, 18, 20, 21, 23, 24 and 26-31 are in this application. Claim 30 has been amended to include that the pulverized above ground parts of the plant *Tinospora cordifolia* are treated with water at an elevated temperature for a period of about 1.5 hours to 2.5 hours. Support for this amendment is found in lines 6 and 7 of paragraph [00042] of the specification. The other amendments to claim 30 will be discussed below.

Applicants maintain that all of the claims of this application should be examined in this application. Applicants submit that when claim 30 is allowed that the method claims must be rejoined in this application because a method of treatment using a new and nonobvious extract is new and nonobvious (MPEP 821.04).

The Examiner has rejected claims 30 and 31 under 35 USC 112, second paragraph. Applicants respectfully traverse this rejection.

Claim 30 has been amended to correct the spelling of *Tinospora cordifolia*. Line 1 of claim 30 has been amended to delete the word "the" before process.Line 2 has been amended to delete the word "the" before pulverized above ground parts. The spelling of the word present has been corrected. The word "the" has been deleted before methanol soluble content of said extract.

Therefore, it is respectfully requested that this rejection be withdrawn.

The Examiner has rejected claims 30 and 31 under 35 USC 102(b) as anticipated by Thatte or, in the alternative, under 35 USC 103(a) as obvious over Thatte et al. as evidenced by Hoffman and Kruger. Applicants respectfully traverse this rejection.

The bane of herbal products is the lack of sufficient standardization in the face of innumerable variables starting from plant species variation through to cultivation processes, plant age at harvesting, season of harvesting and eventually to the process

of production of the extract, which is further subject to a whole host of additional variables. For a herbal extract to find commercial or industrial utility in the modern pharmaceutical environment, it is essential to have an extract that has certain parameters reproducible that are considered essential for standardization. This goal has been met with the claimed invention. The standardized extracts must have the properties defined in claim 30-immunomodularity activity and comparision with the peaks of the LC-MS SIR chromatogram. This is Case 4 as shown in the attached Annexure 1.

The extract of the claimed invention is not the same as the *Tinospora cordifolia* described in Thatte et al. According to the abstract of Thatte and column 2 on page 14, the extract of *Tinospora cordifolia* did not possess *in vitro* bactericidal activity. ("*In vitro* Antimicrobial effect: *Tinospora cordifolia* exhibited no in *vitro* antibacterial effect at any strength. Similarly, the serum from treated animals also showed no antimicrobial effects.) As shown in the attached declaration of Noel J. De Souza, the extracts of this invention have *in vitro* bactericidal activity. Therefore, since the extract of the invention has *in vitro* bacterial activity it is clear that the extract of this invention is not and cannot be the same as the extract of Thatte.

The dry water extract of *Tinospora cordifolia* that was used to prepare the aqueous aqueous solutions that were tested for bactericidal activity as described in the attached declaration were prepared according to the procedure described in paragraph [00042] of this application.

As claimed in claim 30 of this application, the composition comprises an extract of *Tinospora cordifolia* that has one constituent which has a mass spectrometric M+ value of m/z 480 mass units and is present to an extent of not less than 35% of the two identified peak areas of the liquid chromatography mass spectrometry single ion recording (LC-MS SIR) chromatogram, and has a second constituent which has a mass spectrometric M+ value of m/z 341 mass units and is present to an extent of not more than 65% of the two identified peak areas of the LC-MS SIR chromatogram of the

methanol soluble content of said extract. The claimed invention provides for standardization that is neither disclosed nor suggested in Thatte.

Thatte states that the dried, powdered stem was made into a decoction after boiling in water and administered in the dose of 100 mg/kg/d by intragastric tube. It is unclear from this statement to what the 100 mg refers, whether it is 100 mg decoction or decoction made from 100 mg of dry stem powder. Thatte et al. do not state that the decoction is concentrated or evaporated to provide a powder of which 100 mg is given. Thatte does not describe how long the dried powdered stem was boiled in water.

According to claim 30 of this application, the extract is prepared by treating the pulverized above ground parts of the plant *Tinospora cordifolia* with water at an elevated temperature for a period of about 1.5 hours to 2.5 hours. Hoffman describes preparing a decoction by simmering the herb and water mixture for 10 to 15 minutes (p. 23). One skilled in the art would expect that the extract obtained after boiling for 1.5 to 2.5 hours would be different from an extract that is simmered for 10 to 15 minutes. Plants are known to comprise several different constituents of variable solubility in water. Boiling for 1.5 hours in contrast to simmering for 10 to 15 minutes can result in an extract in which the constituents differ in their concentrations depending on their solubility.

In addition, the pulverized above ground parts of the plant is used to prepare the composition of this invention Since, only the stem is used in Thatte, the extracts cannot be the same. Kruger does not disclose the process used to prepare the claimed composition and does not disclose nor suggest the properties of the claimed composition. Therefore, since the plant components, and the process used to prepare the extracts of this invention are different from what is disclosed Thatte, Hoffman and Kruger and the antibacterial properties of the claimed composition differ from those of Thatte, the claimed invention is novel and nonobvious over Thatte and the combination of Thatte, Hoffman and Kruger.

Accordingly, it is respectfully requested that this rejection be withdrawn.

Applicants submit that the present application is in condition for allowance and favorable consideration is respectfully requested.

Respectfully submitted

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